

□ 1909

So (two-thirds being in the affirmative) the rules were suspended and the bill, as amended, was passed.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

### HONOR AMERICA'S GUARD-RESERVE RETIREES ACT

The SPEAKER pro tempore. The unfinished business is the vote on the motion to suspend the rules and pass the bill (H.R. 1384) to amend title 38, United States Code, to recognize the service in the reserve components of certain persons by honoring them with status as veterans under law, on which the yeas and nays were ordered.

The Clerk read the title of the bill.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Pennsylvania (Mr. COSTELLO) that the House suspend the rules and pass the bill.

This is a 5-minute vote.

The vote was taken by electronic device, and there were—yeas 407, nays 0, not voting 26, as follows:

[Roll No. 628]

YEAS—407

Abraham	Castro (TX)	Duncan (TN)
Adams	Chabot	Edwards
Aderholt	Chaffetz	Ellison
Aguilar	Chu, Judy	Ellmers (NC)
Allen	Cicilline	Emmer (MN)
Amash	Clark (MA)	Engel
Ashford	Clarke (NY)	Esty
Babin	Clawson (FL)	Farenthold
Barletta	Clay	Farr
Barr	Clyburn	Fincher
Barton	Coffman	Fitzpatrick
Bass	Cohen	Fleischmann
Beatty	Cole	Fleming
Becerra	Collins (GA)	Flores
Benishek	Collins (NY)	Forbes
Bera	Comstock	Fortenberry
Beyer	Conaway	Foster
Bilirakis	Connolly	Fox
Bishop (GA)	Conyers	Frankel (FL)
Bishop (MI)	Cook	Franks (AZ)
Bishop (UT)	Cooper	Frelinghuysen
Black	Costa	Fudge
Blackburn	Costello (PA)	Gabbard
Blum	Courtney	Gallego
Blumenauer	Cramer	Garamendi
Bonamici	Crawford	Garrett
Bost	Crenshaw	Gibbs
Boustany	Crowley	Gibson
Boyle, Brendan F.	Cuellar	Gohmert
Brady (PA)	Culberson	Goodlatte
Brady (TX)	Cummings	Gosar
Brat	Curbelo (FL)	Gowdy
Bridenstine	Davis (CA)	Graham
Brooks (AL)	Davis, Danny	Granger
Brooks (IN)	Davis, Rodney	Graves (GA)
Brown (FL)	DeGette	Graves (LA)
Brownley (CA)	Delaney	Graves (MO)
Buchanan	DeLauro	Grayson
Buck	DelBene	Green, Al
Bucshon	Denham	Green, Gene
Burgess	Dent	Griffith
Bustos	DeSantis	Grijalva
Butterfield	DeSaulnier	Grothman
Byrne	DesJarlais	Guinta
Calvert	Deutch	Guthrie
Capps	Diaz-Balart	Hahn
Capuano	Dingell	Hanna
Cárdenas	Doggett	Hardy
Carney	Dold	Harper
Carson (IN)	Donovan	Harris
Carter (GA)	Doyle, Michael F.	Hartzler
Carter (TX)	Duckworth	Hastings
Cartwright	Duffy	Heck (NV)
Castor (FL)	Duncan (SC)	Heck (WA)
		Hensarling

Herrera Beutler	McHenry	Sánchez, Linda T.
Hice, Jody B.	McKinley	T.
Higgins	McMorris	Sanford
Hill	Rodgers	Sarbanes
Himes	McNerney	Scalise
Holding	McSally	Schiff
Honda	Meadows	Schrader
Hoyer	Meehan	Schweikert
Huelskamp	Meeks	Scott (VA)
Huffman	Meng	Scott, Austin
Huizenga (MI)	Messer	Sensenbrenner
Hunter	Mica	Serrano
Hurd (TX)	Miller (FL)	Sessions
Hurt (VA)	Miller (MI)	Sewell (AL)
Israel	Moolenaar	Sherman
Issa	Mooney (WV)	Shimkus
Jackson Lee	Moore	Shuster
Jeffries	Moulton	Simpson
Jenkins (KS)	Mullin	Sinema
Jenkins (WV)	Mulvaney	Sires
Johnson (GA)	Murphy (FL)	Slaughter
Johnson (OH)	Murphy (PA)	Smith (MO)
Johnson, E. B.	Nadler	Smith (NE)
Johnson, Sam	Napolitano	Smith (NJ)
Jolly	Neal	Smith (TX)
Jones	Neugebauer	Smith (WA)
Jordan	Newhouse	Speier
Joyce	Noem	Stefanik
Kaptur	Nolan	Stewart
Katko	Norcross	Stivers
Keating	Nugent	Stutzman
Kelly (IL)	Nunes	Swalwell (CA)
Kelly (MS)	O'Rourke	Takano
Kelly (PA)	Olson	Thompson (CA)
Kennedy	Palazzo	Thompson (MS)
Kildee	Pallone	Thompson (PA)
Kilmer	Palmer	Thornberry
Kind	Pascarell	Tiberi
King (NY)	Paulsen	Tipton
Kinzinger (IL)	Payne	Tonko
Kirkpatrick	Pearce	Torres
Kline	Pelosi	Trott
Knight	Perlmutter	Tsongas
Kuster	Perry	Turner
Labrador	Peters	Upton
LaHood	Peterson	Valadao
LaMalfa	Pingree	Van Hollen
Lamborn	Pittenger	Vargas
Lance	Pitts	Veasey
Langevin	Pocan	Vela
Larsen (WA)	Poe (TX)	Velázquez
Larson (CT)	Poliquin	Visclosky
Latta	Polis	Walberg
Lee	Pompeo	Walden
Levin	Posey	Walker
Lewis	Price (NC)	Walorski
Lipinski	Price, Tom	Walters, Mimi
LoBiondo	Quigley	Walz
Loeb sack	Rangel	Wasserman
Lofgren	Ratcliffe	Schultz
Long	Reed	Waters, Maxine
Loudermilk	Reichert	Watson Coleman
Love	Renacci	Weber (TX)
Lowenthal	Ribble	Webster (FL)
Lucas	Rice (NY)	Welch
Luetkemeyer	Rice (SC)	Wenstrup
Lujan Grisham (NM)	Rigell	Westerman
Lujan, Ben Ray (NM)	Roby	Westmoreland
Lummis	Roe (TN)	Williams
Lynch	Rogers (AL)	Wilson (FL)
MacArthur	Rogers (KY)	Wilson (SC)
Maloney	Rokita	Wittman
Carolyn	Rooney (FL)	Womack
Maloney, Sean	Ros-Lehtinen	Woodall
Marino	Roskam	Yarmuth
Massie	Ross	Yoder
Matsui	Rothfus	Yoho
McCarthy	Rouzer	Young (AK)
McCaul	Roybal-Allard	Young (IA)
McClintock	Royce	Young (IN)
McCollum	Ruiz	Zeldin
McDermott	Russell	Zinke
	Ryan (OH)	
	Salmon	

### NOT VOTING—26

Amodei	King (IA)	Rush
Cleaver	Lawrence	Sanchez, Loretta
DeFazio	Lieu, Ted	Schakowsky
Eshoo	Lowey	Scott, David
Fattah	Marchant	Takai
Gutiérrez	McGovern	Titus
Hinojosa	Richmond	Wagner
Hudson	Rohrabacher	Whitfield
Hultgren	Ruppersberger	

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore (during the vote). There are 2 minutes remaining.

□ 1917

So (two-thirds being in the affirmative) the rules were suspended and the bill was passed.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

### PERSONAL EXPLANATION

Mrs. LAWRENCE. Mr. Speaker, I was unable to vote due to the necessity of my attending to representational duties and participation in Michigan. Had I been in attendance, I would have voted: "yes"—H.R. 308—Keep the Promise Act, "yes"—H.R. 1338—Dignified Interment of Our Veterans' Act of 2015, "yes"—H.R. 1384—Honor America's Guard-Reserve Retirees Act.

### PERSONAL EXPLANATION

Ms. SCHAKOWSKY. Mr. Speaker, this evening, I was unavoidably detained and unable to cast votes on the House floor. Had I been present, I would have voted "aye" on H.R. 1338 and H.R. 1384. I would have voted "nay" on H.R. 308.

### PERSONAL EXPLANATION

Mr. FATTAH. Mr. Speaker, on the following rollcall Nos. I would have voted: "no" on rollcall 626, "yes" on rollcall 627, "yes" on rollcall 628.

### PERSONAL EXPLANATION

Mr. DEFAZIO. Mr. Speaker, I was absent on November 16, 2015, due to recovery from eye surgery, and missed the following votes. Had I been present I would have voted:

On Motion to Suspend the Rules and Pass H.R. 308, I would have voted "present."

On Motion to Suspend the Rules and Pass H.R. 1338, I would have voted "aye."

On Motion to Suspend the Rules and Pass H.R. 1384, I would have voted "aye."

### REPORT ON RESOLUTION PROVIDING FOR CONSIDERATION OF H.R. 1737, REFORMING CFPB INDIRECT AUTO FINANCING GUIDANCE ACT; PROVIDING FOR CONSIDERATION OF H.R. 511, TRIBAL LABOR SOVEREIGNTY ACT OF 2015; AND FOR OTHER PURPOSES

Mr. COLE, from the Committee on Rules, submitted a privileged report (Rept. No. 114-340) on the resolution (H. Res. 526) providing for consideration of the bill (H.R. 1737) to nullify certain guidance of the Bureau of Consumer Financial Protection and to provide requirements for guidance issued by the Bureau with respect to indirect auto lending; providing for consideration of the bill (H.R. 511) to clarify the rights of Indians and Indian tribes on Indian lands under the National Labor Relations Act; and for other purposes, which was referred to the House Calendar and ordered to be printed.

# REMOVAL OF NAME OF MEMBER AS COSPONSOR OF H.R. 1694

Mrs. BUSTOS. Mr. Speaker, I ask unanimous consent to remove my name as a cosponsor of H.R. 1694.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Illinois?

There was no objection.

# IMPROVING REGULATORY TRANSPARENCY FOR NEW MEDICAL THERAPIES ACT

Mr. GRIFFITH. Mr. Speaker, I ask unanimous consent to take from the Speaker's table the bill (H.R. 639) to amend the Controlled Substances Act with respect to drug scheduling recommendations by the Secretary of Health and Human Services, and with respect to registration of manufacturers and distributors seeking to conduct clinical testing, with the Senate amendment thereto, and concur in the Senate amendment.

The Clerk read the title of the bill.

The SPEAKER pro tempore. The Clerk will report the Senate amendment.

The Clerk read as follows:

Senate amendment:

Strike all after the enacting clause and insert the following:

## SECTION 1. SHORT TITLE.

This Act may be cited as the "Improving Regulatory Transparency for New Medical Therapies Act".

## SEC. 2. SCHEDULING OF SUBSTANCES INCLUDED IN NEW FDA-APPROVED DRUGS.

(a) EFFECTIVE DATE OF APPROVAL.—

(1) EFFECTIVE DATE OF DRUG APPROVAL.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

"(x) DATE OF APPROVAL IN THE CASE OF RECOMMENDED CONTROLS UNDER THE CSA.—

"(1) IN GENERAL.—In the case of an application under subsection (b) with respect to a drug for which the Secretary provides notice to the sponsor that the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act, approval of such application shall not take effect until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.

"(2) DATE OF APPROVAL.—For purposes of this section, with respect to an application described in paragraph (1), the term 'date of approval' shall mean the later of—

"(A) the date an application under subsection (b) is approved under subsection (c); or

"(B) the date of issuance of the interim final rule controlling the drug."

(2) EFFECTIVE DATE OF APPROVAL OF BIOLOGICAL PRODUCTS.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

"(n) DATE OF APPROVAL IN THE CASE OF RECOMMENDED CONTROLS UNDER THE CSA.—

"(1) IN GENERAL.—In the case of an application under subsection (a) with respect to a biological product for which the Secretary provides notice to the sponsor that the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act, approval of such application shall not take effect until the interim final rule controlling the biological product is issued in accordance with section 201(j) of the Controlled Substances Act.

"(2) DATE OF APPROVAL.—For purposes of this section, with respect to an application described in paragraph (1), references to the date of approval of such application, or licensure of the product subject to such application, shall mean the later of—

"(A) the date an application is approved under subsection (a); or

"(B) the date of issuance of the interim final rule controlling the biological product."

(3) EFFECTIVE DATE OF APPROVAL OF ANIMAL DRUGS.—

(A) IN GENERAL.—Section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b) is amended by adding at the end the following:

"(q) DATE OF APPROVAL IN THE CASE OF RECOMMENDED CONTROLS UNDER THE CSA.—

"(1) IN GENERAL.—In the case of an application under subsection (b) with respect to a drug for which the Secretary provides notice to the sponsor that the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act, approval of such application shall not take effect until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.

"(2) DATE OF APPROVAL.—For purposes of this section, with respect to an application described in paragraph (1), the term 'date of approval' shall mean the later of—

"(A) the date an application under subsection (b) is approved under subsection (c); or

"(B) the date of issuance of the interim final rule controlling the drug."

(B) CONDITIONAL APPROVAL.—Section 571(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ccc(d)) is amended by adding at the end the following:

"(4)(A) In the case of an application under subsection (a) with respect to a drug for which the Secretary provides notice to the sponsor that the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act, conditional approval of such application shall not take effect until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.

"(B) For purposes of this section, with respect to an application described in subparagraph (A), the term 'date of approval' shall mean the later of—

"(i) the date an application under subsection (a) is conditionally approved under subsection (b); or

"(ii) the date of issuance of the interim final rule controlling the drug."

(C) INDEXING OF LEGALLY MARKETED UNAPPROVED NEW ANIMAL DRUGS.—Section 572 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ccc-1) is amended by adding at the end the following:

"(k) In the case of a request under subsection (d) to add a drug to the index under subsection (a) with respect to a drug for which the Secretary provides notice to the person filing the request that the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act, a determination to grant the request to add such drug to the index shall not take effect until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act."

(4) DATE OF APPROVAL FOR DESIGNATED NEW ANIMAL DRUGS.—Section 573(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ccc-2(c)) is amended by adding at the end the following:

"(3) For purposes of determining the 7-year period of exclusivity under paragraph (1) for a drug for which the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act, the drug shall not be considered approved or conditionally approved until the date that the interim final rule controlling the drug

is issued in accordance with section 201(j) of the Controlled Substances Act."

(b) SCHEDULING OF NEWLY APPROVED DRUGS.—Section 201 of the Controlled Substances Act (21 U.S.C. 811) is amended by inserting after subsection (i) the following:

"(j)(1) With respect to a drug referred to in subsection (f), if the Secretary of Health and Human Services recommends that the Attorney General control the drug in schedule II, III, IV, or V pursuant to subsections (a) and (b), the Attorney General shall, not later than 90 days after the date described in paragraph (2), issue an interim final rule controlling the drug in accordance with such subsections and section 202(b) using the procedures described in paragraph (3).

"(2) The date described in this paragraph shall be the later of—

"(A) the date on which the Attorney General receives the scientific and medical evaluation and the scheduling recommendation from the Secretary of Health and Human Services in accordance with subsection (b); or

"(B) the date on which the Attorney General receives notification from the Secretary of Health and Human Services that the Secretary has approved an application under section 505(c), 512, or 571 of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act, or indexed a drug under section 572 of the Federal Food, Drug, and Cosmetic Act, with respect to the drug described in paragraph (1).

"(3) A rule issued by the Attorney General under paragraph (1) shall become immediately effective as an interim final rule without requiring the Attorney General to demonstrate good cause therefor. The interim final rule shall give interested persons the opportunity to comment and to request a hearing. After the conclusion of such proceedings, the Attorney General shall issue a final rule in accordance with the scheduling criteria of subsections (b), (c), and (d) of this section and section 202(b)."

(c) EXTENSION OF PATENT TERM.—Section 156 of title 35, United States Code, is amended—

(1) in subsection (d)(1), in the matter preceding subparagraph (A), by inserting ", or in the case of a drug product described in subsection (i), within the sixty-day period beginning on the covered date (as defined in subsection (i))" after "marketing or use"; and

(2) by adding at the end the following:

"(i)(1) For purposes of this section, if the Secretary of Health and Human Services provides notice to the sponsor of an application or request for approval, conditional approval, or indexing of a drug product for which the Secretary intends to recommend controls under the Controlled Substances Act, beginning on the covered date, the drug product shall be considered to—

"(A) have been approved or indexed under the relevant provision of the Public Health Service Act or Federal Food, Drug, and Cosmetic Act; and

"(B) have permission for commercial marketing or use.

"(2) In this subsection, the term 'covered date' means the later of—

"(A) the date an application is approved—

"(i) under section 351(a)(2)(C) of the Public Health Service Act; or

"(ii) under section 505(b) or 512(c) of the Federal Food, Drug, and Cosmetic Act;

"(B) the date an application is conditionally approved under section 571(b) of the Federal Food, Drug, and Cosmetic Act;

"(C) the date a request for indexing is granted under section 572(d) of the Federal Food, Drug, and Cosmetic Act; or

"(D) the date of issuance of the interim final rule controlling the drug under section 201(j) of the Controlled Substances Act."

## SEC. 3. ENHANCING NEW DRUG DEVELOPMENT.

Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended by adding at the end the following: